REMARKS

Claims 1, 2 and 25-45 have been examined and stand rejected under 35 U.S.C. §§ 112, 102 and 103.

Claims 3-24 had been cancelled in the Preliminary Amendment, and claims numbered 3-24 which had been presented with amendments in a Supplemental Preliminary Amendment (which was not entered) have been presented herein as Claim 46-67.

Applicant has now amended Claims 1, 2, 27 and 28.

Thus, upon entry hereof, the claims will be 1, 2, and 25-67, with Claim 1 being independent.

Section 112 Rejections

Claims 1, 2 and 25-45 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The reasoning behind this rejection is set forth in the Action, at page 2. Those claims also stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The reasoning behind this rejection is set forth in the Action, at pages 2-3.

Applicant traverses the bases for the Section 112, first paragraph, rejections.

Applicant points out that the citrate esters described and claimed in the subject application are covered by two

different generalized formulae, either "I" or from the combination of various structural elements selected from "A", "B" and "C". See specification, pages 10-11. The particular ones the Examiner has referred to (as being incorrect) are built up from "A", "B" and "C". That is, triethyl-O-acetylcitrate would be the combination B-A-B, with R = C_2H_5 (= ethyl); R' = $C(O)CH_3$; and the remaining free valences are saturated with -H. The tributyl-O-acetyl citrate would be the same, with the only difference being that R = butyl.

Applicant further points out that the formulae "I" and "A,B,C" are alternatives; the plasticizer should either fall into the definition given by formula "I" or the definition given by the "A,B,C" combination, but not both. It appears from the rejection that this has been overlooked.

Accordingly, Applicant submits that reconsideration and withdrawal of the Section 112, first paragraph, rejections are therefore appropriate as regards the nomenclature issue.

Applicant has also amended Claims 1, 2, 27 and 28 to recite proper Markush language and correct a typographical error.

Applicant submits that the Section 112, second paragraph, rejections should no longer be maintained and as such

reconsideration and withdrawal thereof are respectfully requested.

Section 102(b) Rejections

Claims 1, 2, 25, 26, 32-36 and 39-45 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,364,876 (Kimura, et al.) for the reasons given at page 4, third full paragraph of the Action.

Applicant traverses the Section 102(b) rejections.

As the Examiner is aware, the invention is defined in its broadest sense by Claim 1, which in substance reads a cyanoacrylate composition comprising at least one lower cyanoacrylate monomer component selected from ethyl cyanoacrylate and methoxycyanoacrylate; at least one higher cyanoacrylate monomer component in an amount greater than 12% by weight based on the total weight of the combination of the lower cyanoacrylate monomer and the higher cyanoacrylate monomer, and the higher cyanoacrylate monomer, and a plasticiser component is present in the composition in an amount between about 15 to about 40% by weight of the composition, and the plasticiser component has an Ap/Po ratio in the range of about 1 to less than about 6, provided the plasticiser component does not include pentaerythritoltetrabenzoate as the sole plasticiser.

Kimura in contrast is directed to and claims a 2-cyanoacrylate represented by the specified formula, where R^1 is a 1,2-alkylene group having 2-4 carbon atoms, R^2 is an alkylene group having 2-4 carbon atoms and R^3 is an alkyl group having 1-6 carbon atoms.

The Examiner is correct in that it is known in the art to use mixtures of cyanoacrylates. The Examiner is correct in that is also known in the art to use plasticisers, some of which have an Ap/Po ratio which is specified in Claim 1. And Applicant does not dispute that the present invention employs conventional plasticisers.

Having said that, however, Applicant invites the Examiner's attention to the invention defined by Claim 1 and requests that he reconsider the Section 102 rejection. In particular, Claim 1 is not directed to any arbitrary selection of high and low molecular weight cyanoacrylate mixtures. Rather, Claim 1 of the application has been specifically limited by a lower cyanoacrylate selected from only ethyl cyanoacrylate or methoxy cyanoacrylate. Further, the higher cyanoacrylate monomer has also been limited by only those specified in the list presented in Claim 1.

In addition, Claim 1 specifies that a plasticiser be present. Claim 1 goes so far as to specify a certain type of

plasticiser (specified by Ap/Po ratio and being miscible in the mixture of lower and higher cyanoacrylate). The composition of Claim 1 even has a specified amount of the plasticiser.

Given the specificity by which Claim 1 has defined the present invention, Applicant submits that Kimura fails to teach each and every recitation thereof, which as the Examiner knows, must occur for a proper Section 102 rejection to be advanced.

Accordingly, Applicant submits that the Section 102(b) rejection based on Kimura cannot stand and as such requests reconsideration and withdrawal thereof.

Section 103(a) Rejections

Claims 1, 2, 25-27, 29, 30, 32-41, 43 and 45 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,998,472 (Berger) for the reasons given at pages 3-4, paragraph 4. Claims 1, 2, 25-31, 32-36 and 39-45 stand rejected under Section 103(a) as allegedly being unpatentable over U.S. Patent No. 4,364,876 Kimura in view of Joyner, Berger, Malofsky, Hickey and Hogensen for the reasons given at pages 4-5 (paragraph bridging pages 4 and first two paragraphs of page 5) of the Action.

Applicant traverses the Section 103(a) rejections.

Initially, Applicant notes that since Claim 28 has not been rejected under either Sections 102(b) or 103(a), Applicant understands this claim therefor to be allowable, as the Section 112 matters have been addressed above. As such, Applicant respectfully reserves the right to rewrite this claim in independent form.

The recitations of Claim 1 requires a specific a combination of plasticiser properties/plasticiser amount/only two lower cyanoacrylate possibilities/and only certain higher cyanoacrylate possibilities. According to the invention defined by Claim 1, all of these conditions must be present in order to see desired flexibility/transparency over time, as Applicant has demonstrated.

Put another way, it is the specific parameters recited in Claim 1 that allow for reproducibility of the results achieved with the present invention. Only with the present invention, such as is defined by Claim 1, can one obtain cyanoacrylate compositions which consistently have the properties desired, namely retained flexibility over time, and retention of transparency of the composition over time.

The Examiner has determined that the claims of

the present application are obvious over Berger. This determination is incorrect.

The Tables of the present application demonstrate that the desirable properties of compositions of the invention are not predictable from any of the cited documents of record, whether alone or in any combination.

Suggesting as the Action does that the disclosures of the cited documents to move between different amounts and types of plasticiser and/or between possible mixtures of cyanoacrylates to disclose, teach or suggest the invention as defined by Claim 1 amounts to a hindsight examination thereof by picking and choosing selected portions of these documents, while ignoring salient teachings of the respective disclosures.

The combination of the specific criteria recited in Claim 1 is not contemplated in any one of the cited documents of record and there is no direction in those cited documents that would lead one of ordinary skill in the art to that recited criteria.

For instance, Table 1 of the present application (specification, page 21), shows the flexibility/turbidity of monomer and/or standard grade unmodified adhesives. It is clear from Table 1 that none of the compositions from the table have desirable properties.

Table 2 demonstrates the effect of adding plasticiser to cyanoacrylate. It is clear from this table that while certain of the compositions demonstrate desirable properties, many of the compositions do not. In fact, most of the compositions fail on at least one of the desirable properties most usually retention of flexibility (in this case after 10 weeks).

Table 3 in contrast includes many of the examples of formulations of the present invention (others are included for comparative purposes). It is clear from Table 3 that in accordance with the present invention as defined by Claim 1, one of ordinary skill in the art can achieve consistently reproducible results, e.g., desired flexibility (and transparency/lack of turbidity) over time.

Table 4 provided further examples of the present invention by using combinations of plasticisers.

Table 5 shows that the bond strength formed with formulations of the present invention are comparable to standard cyanoacrylate compositions or unmodified cyanoacrylate formulations (control values). This property is often one compromised by adding components to cyanoacrylate formulations, and here it is seen that it is retained.

Table 6 provides a convenient summary of the results, and the various tables are discussed in detail at page 29-33 of the Specification.

In short, the specific selection of the lower and higher cyanoacrylates, together with the plasticiser component having a specific property and also being present in certain amounts, is fundamental to the success of the present invention as defined by Claim 1 so as to achieve the results observed, particularly in a reproducible manner. This teaching cannot be derived, nor is it suggested, from any of the documents cited.

Berger, in contrast to that which is defined by the present invention, is directed to and claims an alkyl cyanoacrylate ester composition of C_1 to C_8 cyanoacrylate ester monomers or oligomers and a sufficient amount of C_{10} to C_{12} alkyl cyanoacrylate ester monomers or oligomers to provide enhanced flexibility to the polymeric film formed on mammalian skin as compared to the polymeric film formed from the C_1 to C_8 alkyl cyanoacrylate ester, while maintaining the liquid characteristics of the composition at room temperature. The C_{10} to C_{12} alkyl cyanoacrylate ester is specified as a decyl, undecyl or dodecyl ester.

Berger does not however disclose, teach or suggest the specific combination of recitations set forth in Claim 1.

Moreover, the plasticiser (dioctylphthalate) of Berger, Example 1 has an Ap/Po ratio of 8, which lies outside the parameters set forth in Claim 1. Further, Berger does not disclose, teach or suggest the ability of retaining flexibility over time (see the Tables of the subject application which demonstrate loss of flexibility over time in compositions which do not meet the parameters set forth in Claim 1). And in any event Example 1 of Berger does not disclose, teach or suggest the combination of lower and higher cyanoacrylate as specified in Claim 1.

Since Berger provides no disclosure, teaching or suggestion that would lead one of ordinary skill in the art to reach the invention as defined by Claim 1, Applicant requests that the Section 103(a) rejection based on Berger no longer be maintained.

The Section 103(a) rejection based on Kimura and a combination of secondary references should likewise no longer be maintained either.

Joyner is directed to and claims a composite article having at least two elements adhered together by an *in situ* polymerized layer of an adhesive composition. The adhesive composition comprises monomeric α-cyanoacrylate ester, where the ester group includes alkyl groups of C_1-C_8, and 1-20% by weight based on the weight of the α-cyanoacrylate ester of at least one

plasticizer selected from alkyl esters of aliphalic monocarboxylic acids, where the linkage between the ester and electron withdrawing group includes alkyl groups of C_1-C_{17} carbon atoms, and where the ester includes alkyl groups of C_1-C_8 carbon atoms.

Malofsky is directed to and claims a polymerizable monomeric adhesive composition of a polymerizable 1,1-disubstituted ethylene monomer (such as cyanoacrylate) in a liquid phase and in a vapor phase, a vapor phase anionic stabilizer, and a liquid phase anionic stabilizer. The liquid phase anionic stabilizer is a very strong mineral acid.

Hickey is directed to and claims a method of making a sterile adhesive composition that includes placing a mixture of a polymerizable 1,1-disubstituted ethylene monomer (such as cyanoacrylate) and a thickening agent in a container, where the thickening agent is soluble in the monomer at room temperature, sealing the container, and sterilizing the mixture in the container.

Hogenson is directed to and claims a covered stent for use in the body of a living being, the covered stent having a stent and a cover.

Kimura, discussed above, is primarily concerned with providing what he describes as novel compounds. Kimura, Example

9 does not suggest that the addition of a plasticiser is necessary (the plasticiser is only optional, according to Kimura at column 5). In Applicant's invention as defined by Claim 1, without the required plasticizer as set forth therein, the consistent results were not observed, as explained above.

Further, the plasticisers listed in Kimura include for example dioctylphthalate which, as with Berger, is excluded by the Ap/Po ratio set forth in Claim 1. Kimura discloses also trioctyl trimellitate which also has an Ap/Po ratio of 8 [see specification, pages 17-18 of the present invention and Table 2 (Examples 29-30 and 33) and Table 6], which again lies outside of the defined recitation of Claim 1.

Kimura also discloses specific plasticisers and specific 2-cyanoacrylates <u>separately</u> as flexibilising components for Kimura's cyanoacrylates, rather than in combination, as Applicant has done.

None of these secondary documents remedy the deficiencies of Kimura or Berger as primary references. And none of these documents provide any suggestion to look toward the other to be combined therewith. The only way in which the documents may have been combined is due to hindsight reconstruction, which as the Examiner is aware is improper.

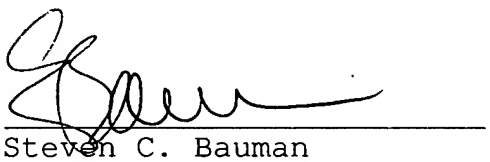
For at least these reasons, the Section 103 claim rejections should no longer be maintained, and prompt passage of issuance of the subject application is requested.

CONCLUSION

In view of the above, favorable reconsideration and passage to issue of the present case are respectfully requested.

Applicant's undersigned attorney may be reached by telephone at (860) 571-5001 or by facsimile at (860) 571-5028. All correspondence should be directed to the address given below.

Respectfully submitted,



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